



MAY - 1 2000

K000682

3.0 Summary of Safety and Effectiveness Information:

Summary of Safety and Effectiveness Information

SPONSOR: Synthes (USA)
1690 Russell Road
Paoli, PA 19301

(610) 647-9700

CONTACT: Angela Silvestri

DEVICE NAME:: Synthes Large Fragment Dynamic Compression Locking (DCL) System

DEVICE CLASSIFICATION: 21 CFR 888.3030 Single/multiple component metallic bone fixation appliances and accessories and 888.3040 Smooth/threaded metallic bone fixation fastener.

PREDICATE DEVICE: Synthes Broad and Narrow Dynamic Compression Plates
Synthes Anatomical Locking Plate System

DESCRIPTION OF DEVICE: The Large Fragment DCL system consists of limited-contact profile plates in broad and narrow sizes, which include combination dynamic compression/locking screw holes. The plates accept 4.5 mm cortex, 6.5 mm cancellous, 4.5 mm cannulated, 7.0 mm cannulated, and 5.0 mm locking screws. This device is manufactured in either stainless steel or titanium.

INDICATIONS: Synthes Large Fragment DCL is intended for fixation of various long bones, such as the humerus, femur and tibia. It is also for use in fixation of osteopenic bone and fixation of non-unions or malunions.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

MAY - 1 2000

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Angela J. Silvestri
Manager, Regulatory Affairs
SYNTHES (USA)
1690 Russell Road
Post Office Box 1766
Paoli, Pennsylvania 19301-1222

Re: K000682
Trade Name: Large Fragment Dynamic Compression Locking (DCL) System
Regulatory Class: II
Product Code: KTT
Dated: February 25, 2000
Received: February 29, 2000

Dear Ms. Silvestri:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

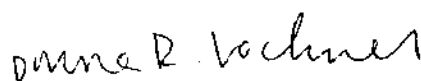
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

Page 2 – Ms. Angela J. Silvestri

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,


Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure



1.0 Indications for Use Statement

Page 1 of 1

510(k) Number (if known): K000682

Device Name: Synthes (USA) Large Fragment Dynamic Compression Locking (DCL) System

Indications for use:

Synthes Large Fragment DCL is intended for fixation of various long bones, such as the humerus, femur and tibia. It is also for use in fixation of osteopenic bone and fixation of non-unions or malunions.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ☒
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

Dennis R. Kachner
(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K000682

Large Fragment Dynamic Compression
Locking System 510(k)
Synthes (USA)

Confidential

000003